



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

RB  
rec'd  
3/23/94

14

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**MEMORANDUM**

**SUBJECT:** Cryolite. Magnitude of the Residue in Tomatoes and Peppers. Residue Analytical Method. Reregistration Case No. 0087. Chemical No. 075101. MRID #42630001, 42659301, and 42656901. DP Barcodes D188947 and D188944. CBRS #11,521 and 11,528.

**FROM:** Steven A. Knizner, Chemist *St. A. Knizner*  
Special Review Section I  
Chemistry Branch II - Reregistration Support  
Health Effects Division (7509C)

**THRU:** Andrew Rathman, Section Head *AR*  
Special Review Section 1  
Chemistry Branch II - Reregistration Support  
Health Effects Division (7509C)

**TO:** Brigid Lowery, PM Team 72  
Special Review and Reregistration Division (7508W)

The Cryolite Reregistration Standard Update dated 5/16/91 required additional residue data for peppers and tomatoes. In response, Elf Atochem North America, Inc. and Gowan Company submitted (under CBRS Nos. 11521 and 11528) data pertaining to the magnitude of the residue of cryolite in/on peppers (1993; MRID 42659301) and tomatoes (1993; MRID 42656901). In addition, Atochem and Gowan have submitted (CBRS No. 11521, 1993; MRID 42630001) revisions to a method for analysis of fluoride residues of cryolite in animal tissues in response to a CBTS review (PP#9F3739, 5/19/92, F. Griffith) which addresses the acceptability of the method for publication in the Pesticide Analytical Manual (PAM) Vol. II. These submissions have been reviewed by Dynamac under contract to the Agency, and have been revised to reflect Branch Policies.

The submitted revisions of the method, Atochem Method No. BR-010-00, are not fully adequate. Change 2 on page 7 of MRID #4263001 (Atochem Study Number BR-92-55) does not adequately revise the paragraph in question to indicate that background correction applies only to tissues instead of crops. Instead of reading "... (e.g., tissues, water, soil, and crops) ..." the sentence should read "... (e.g., tissues) ...". Following receipt of a method



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with this change, the method may be used as an enforcement method for the determination of fluoride residues of cryolite in animal tissues and the method will be forwarded to FDA's Technical Editing Group for publication in PAM Vol. II.

The submitted field trial data for peppers are not adequate because data reflecting application at 1x (48 lb ai/A/application) were not provided. In addition, the registrant must revise the product label(s) to specify a PHI and a maximum number of applications per growing season or a maximum seasonal rate for all formulations. The available data indicate that fluoride residues of cryolite will not exceed the established tolerance of 7.0 ppm in/on peppers harvested 14 days following two foliar applications of the 96% WP at ca. 0.2x (11.5 lb ai/A/application) the maximum registered single application rate. The data requirements of the Cryolite Update pertaining to peppers remain outstanding.

The submitted field trial data for tomatoes are not adequate because data reflecting application at 1x (48 lb ai/A/application) were not provided. In addition, the registrant must revise the product label(s) to specify a PHI and a maximum number of applications per season or a maximum seasonal rate for all formulations. The available data indicate that fluoride residues of cryolite will not exceed the established tolerance of 7.0 ppm in/on tomatoes harvested 14 days following four foliar applications of the 96% WP formulation at 0.3x (15.4 lb ai/A/application) the maximum registered single application rate.

The following options are available to the registrant:

#### Peppers

- 1) Revise all product labels to permit two applications of cryolite at 11.5 lb ai/A/application, with 7 days between applications, and a 14 day PHI. In this case, the submitted data are adequate - no additional residue data for cryolite in/on peppers are required; or,
- 2) Submit new field trial studies that accurately reflect current label instructions (maximum number of applications and PHI must be specified).

#### Tomatoes

- 1) Revise all product labels to permit four applications of cryolite at 15.4 lb ai/A/application, with 7 days between applications, and a 14 day PHI. In this case, the submitted data are adequate - no additional residue data for cryolite in/on tomatoes are required; or,
- 2) Submit new field trial studies that accurately reflect current label instructions (maximum number of applications and PHI must be specified).

**DYNAMAC**  
**CORPORATION**  
Environmental Services

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Final Report

**CRYOLITE**  
**Shaughnessy No. 075101; Case 0087**  
**(CBRS Nos. 11521 & 11528**  
**DP Barcodes D188947 & D188944)**

**TASK 4**  
**Registrant's Response to Residue**  
**Chemistry Data Requirements**

May 18, 1993

Contract No. 68-D2-0053

**Submitted to:**

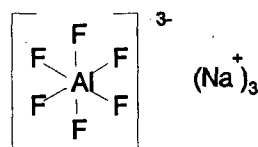
U.S. Environmental Protection Agency  
Arlington, VA 22202

**Submitted by:**

Dynamac Corporation  
The Dynamac Building  
2275 Research Boulevard  
Rockville, MD 20850-3268

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## CRYOLITE



Shaughnessy No. 075101; Case 0087

(CBRS No. 11521; DP Barcode D188947)

(CBRS No. 11528; DP Barcode D188944)

Task 4

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

The Cryolite Reregistration Standard Update dated 5/16/91 requires additional residue data for peppers and tomatoes. In response, Elf Atochem North America, Inc. and Gowan Company submitted (under CBRS Nos. 11521 and 11528) data pertaining to the magnitude of the residue of cryolite in/on peppers (1993; MRID 42659301) and tomatoes (1993; MRID 42656901). In addition, Atochem and Gowan have submitted (CBRS No. 11521, 1993; MRID 42630001) revisions to a method for analysis of fluoride residues of cryolite in animal tissues in response to a CBTS review (PP#9F3739, 5/19/92, F. Griffith) which addresses the acceptability of the method for publication in the Pesticide Analytical Manual (PAM) Vol. II. These submissions are reviewed here for adequacy in fulfilling the outstanding residue chemistry data requirements.

The qualitative nature of the residue in plants is adequately understood; cryolite residues in/on plant commodities are expected to be inorganic surface residues of the parent compound. The requirement for data depicting the qualitative nature of residue in animals has been waived because the Agency has concluded that cryolite metabolism in animals and in man is the same as free fluoride metabolism.

Tolerances for residues of cryolite in/on plant commodities are currently expressed as combined residues of the insecticidal fluorine compounds cryolite and synthetic cryolite (sodium aluminum fluoride) [40 CFR §180.145(a) and (b)]. There are no tolerances for animal commodities. Adequate methodology is available for the enforcement of tolerances; PAM Vol. II lists Method I for the determination of fluoride residues of cryolite in/on plant commodities. No Codex MRLs exist for residues of cryolite; therefore there is no question of compatibility with respect to Codex/U.S. tolerances.

The Conclusions and Recommendations stated in this document pertain only to the submissions listed above. Other data requirements stated in the Cryolite Update, dated 5/16/91, are not addressed herein.

## RECOMMENDATIONS

Concerning the magnitude of the residue in peppers and tomatoes studies, the following options are available to the registrant:

### Peppers

- 1) Revise all product labels to permit two applications of cryolite at 11.5 lb ai/A/application, with 7 days between applications, and a 14 day PHI. In this case, the submitted data are adequate - no additional residue data for cryolite in/on peppers are required; or,
- 2) Submit new field trial studies that accurately reflect current label instructions (maximum number of applications and PHI must be specified).

### Tomatoes

- 1) Revise all product labels to permit four applications of cryolite at 15.4 lb ai/A/application, with 7 days between applications, and a 14 day PHI. In this case, the submitted data are adequate - no additional residue data for cryolite in/on tomatoes are required; or,
- 2) Submit new field trial studies that accurately reflect current label instructions (maximum number of applications and PHI must be specified).

The submitted revisions of the analytical method, Atochem Method No. BR-010-00, are not adequate. See Conclusion 1 for details.

## CONCLUSIONS

1. Residue analytical method: The submitted revisions of the method, Atochem Method No. BR-010-00, are not adequate. Change 2 on page 7 of MRID #4263001 (Atochem Study Number BR-92-55) does not adequately revise the paragraph in question to indicate that background correction applies only to tissues and not crops. Instead of reading "... (e.g., tissues, water, soil, and crops)..." the sentence should read "... (e.g., tissues)..." Following receipt of a method with this change, the method may be used as an enforcement method for the determination of fluoride residues of cryolite in animal tissues and the method will be forwarded to FDA's Technical Editing Group for publication in PAM Vol. II.
2. Magnitude of the residue in peppers: The submitted field trial data for peppers are not adequate because data reflecting application at 1x (48 lb ai/A/application) were not provided. In addition, current product label(s) do not specify a PHI and a maximum number of applications per growing season or a maximum seasonal rate for all formulations. The available data indicate that fluoride residues of cryolite will not exceed the established tolerance of 7.0 ppm in/on peppers harvested 14 days following two foliar applications of the 96% WP at ca. 0.2x (11.5 lb ai/A/application) the maximum registered single application rate. The data requirements of the Cryolite Update pertaining to peppers remain outstanding. If cryolite labels are modified to reflect applications used in the submitted study, no additional data for peppers are required.
3. Magnitude of the residue in tomatoes: The submitted field trial data for tomatoes are not adequate because data reflecting application at 1x (48 lb ai/A/application) were not provided. In addition, the current product label(s) do not specify a PHI and a maximum number of applications per season or a maximum seasonal rate for all formulations. The available data indicate that fluoride residues of cryolite will not exceed the established tolerance of 7.0 ppm

in/on tomatoes harvested 14 days following four foliar applications of the 96% WP formulation at 0.3x (15.4 lb ai/A/application) the maximum registered single application rate. If cryolite labels are modified to reflect applications used in the submitted study, no additional data for tomatoes are required.

## DETAILED CONSIDERATIONS

### Residue Analytical Methods

Samples of tomatoes and peppers from the submitted field trials were analyzed for fluoride residues of cryolite using an ammonium hydroxide/fluoride-specific electrode method (Atochem Method No. BR-006-01, revised 5/25/89). This method was previously described in the Cryolite Update dated 5/16/91 and was deemed adequate for data collection. Briefly, samples are extracted three times with water:58-60% ammonium hydroxide (1:1; v:v) and filtered. The pooled extracts are refluxed for 30 minutes and then concentrated by evaporation. The pH is adjusted to 5.5 using a mixed acetate buffer and a total ionic strength adjustment buffer (TISAB) is added. The method determines residues as fluoride using a fluoride-specific detector. The detection limit is 0.27 ppm fluoride. Analyses were conducted by McKenzie Laboratories, Inc. (Phoenix, AZ). The registrant submitted concurrent method recovery data from untreated samples of peppers and tomatoes fortified with cryolite at 0.5-15.0 ppm; results are presented in Table 1. Sample calculations and representative chromatograms were provided in the submission. We note that residues of fluoride are converted to residues of cryolite by multiplying by 1.84. The method recovery data indicate that the ammonium hydroxide/fluoride-specific electrode method (Atochem Method No. BR-006-01) is adequate for residue data collection for peppers and tomatoes.

Table 1. Concurrent recoveries of cryolite from fortified control samples of peppers and tomatoes analyzed by the  $\text{NH}_4\text{OH}$ /fluoride-specific electrode method (Atochem Method No. BR-006-01).

Commodity	Fortification Level (ppm)	Percent Recovery <sup>a</sup>
Peppers	0.5	74.0
	1.0	87.9
	5.0	77.0-110 <sup>b</sup>
	10.0	83.8
	15.0	79.8
Tomatoes	0.5	92
	1.0	101
	5.0	93.2-113 <sup>b</sup>
	10.0	100
	15.0	101

<sup>a</sup> One sample at each fortification level unless otherwise specified. Percent recoveries were corrected for fluoride levels in controls of 1.69-3.60 ppm in peppers and 2.48-3.96 ppm in tomatoes.

<sup>b</sup> Three samples.

A CBTS memorandum (PP#9F3739, 5/19/92, F. Griffith) addresses the acceptability of a microdiffusion and fluoride-specific electrode method (Atochem Method No. BR-010-00) for

determination of fluoride in animal tissues for publication in PAM Vol. II. The memorandum requires the following revisions to the method: (i) a better description of the preparation of the cryolite standard solution; (ii) revision of a paragraph describing preparation of a sample blank to correct for background fluoride residues; and (iii) correction of an error in an example calculation for fluoride in control samples. The memorandum concluded that method BR-010-00 is suitable for collection of cryolite or fluoride residue data.

In response, Atochem and Gowan (1993; MRID 42630001) have submitted a revised version of method BR-010-00, which incorporates the changes suggested by CBTS. The revisions were:

- (i) Preparation of standard solution: The preparation of the standard solution was described. First a 1 mg/mL stock solution of cryolite is prepared by dissolving 0.1 g of cryolite in 100 mL of deionized or distilled water. Then 1.0 mL of the stock solution is diluted to 100 mL using deionized water to prepare a working solution with a concentration of 10 µg/mL of cryolite. Using the working solution, a set of fortification standards containing 0.01, 0.05, 0.1, 0.5, 1.0, and 5.0 µg/mL are prepared.
- (ii) Background correction: Change 2 on page 7 of MRID #4263001 (Atochem Study Number BR-92-55) does not adequately revise the paragraph in question to indicate that background correction applies only to tissues and not crops. Instead of reading "... (e.g., tissues, water, soil, and crops) ..." the sentence should read "... (e.g., tissues) ...".
- (iii) Quantification calculations: The example calculation was revised to show that the ppm fluoride in the control sample would be 0.47 µg/g instead of 0.07 µg/g as follows:

$$0.09 \mu\text{g/mL} \times 2.0 \text{ mL} \times \frac{1}{0.3815 \text{ g}} = 0.47 \mu\text{g/g}$$

The submitted revisions are not fully adequate. Following receipt of a method with the change noted in (ii) above, the method may be used as an enforcement method for the determination of fluoride residues of cryolite in animal tissues and the method will be forwarded to FDA's Technical Editing Group for publication in PAM Vol. II.

#### Storage Stability Data

Samples of peppers and tomatoes from the submitted field residue studies were stored frozen at ca. -20 C for 19 and 8 months, respectively, prior to analysis. The Cryolite Update, dated 5/16/91 concludes that data pertaining to the storage stability of cryolite in plant matrices are not required because cryolite is a naturally occurring mineral and is not expected to degrade during storage.

#### Magnitude of the Residue in Peppers

A tolerance of 7.0 ppm has been established for the combined residues of the insecticidal fluorine compounds cryolite and synthetic cryolite (sodium aluminum fluoride) in/on peppers [40 CFR §180.145(a)].

A 96% WP and a 96% WP/D formulation are registered for multiple foliar applications to peppers at 24-48 lbs ai/A/application. The 50 and 72% D formulations are registered for approximately six foliar applications to peppers at 13-30 lb ai/A/application at 5-day intervals starting at first fruit set. Applications may be made using ground or aerial equipment. No applications may be made under

drift conditions, in irrigation systems, or in combination with lime. Excess residues on edible portions are to be removed by washing, brushing, or by other effective means. No PHI has been established. No maximum seasonal rates or maximum number of applications per growing season have been established except as noted for the 50% and 72% D formulations. [These use directions were obtained from the label for EPA Reg. No. 4581-116 accepted 9/14/92 and from the following product labels certified and submitted in response to the 10/6/89 DCI for Lists A and B product labels: EPA Reg. Nos. 10163-22, 10163-40, and 10163-41. We note that these use directions are not in agreement with proposed labels submitted by Atochem and Gowan in 1990 and reviewed in the Cryolite Update dated 5/16/91.]

Atochem and Gowan (1993; MRID 42659301) submitted data from 12 tests conducted in CA(3), DE(1), FL(2), NC(1), NJ(1), SC(1), TX(2), and WI(1) depicting fluoride residues of cryolite in/on peppers harvested 14 days following the last of two postemergence foliar broadcast applications of the 96% WP formulation at 11.5 lb ai/A/application (ca. 0.2x the maximum registered single application rate). Applications were made at 7- to 9-day intervals to peppers bearing immature and mature fruit using ground (33.1-55.6 gal/A of finished spray) and aerial (6.0-10.0 gal/A of finished spray) equipment. The results of the pepper field trials are presented in Table 2. Apparent residues in/on untreated samples were 1.69-3.60 ppm. No explanation was provided by the registrant regarding the presence of detectable residues in the control samples. However, it should be noted that fluoride is widely distributed in the earth's crust (ca. 0.03%). Samples were frozen immediately after collection and stored at ca. -20 C for up to 19 months. Samples were analyzed for fluoride residues of cryolite using Atochem Method No. BR-006-01.

Table 2. Fluoride residues of cryolite in/on peppers following two applications of the 96% WP formulation at ca. 0.2x the maximum registered single application rate.

Equipment	Test States	Number of Samples	Cryolite, ppm <sup>a</sup>
Aerial	CA, FL	3	2.32-3.58
Ground	CA, FL, MD, NC, NJ, SC, TX, WI	9	2.00-5.81
Control	CA, FL, NC, NJ, TX, WI	7	1.69-3.60 <sup>b</sup>

<sup>a</sup> Residue values were not corrected for method recoveries and were not corrected for fluoride levels in controls.

<sup>b</sup> Although control samples were generated for all trials, control samples were not analyzed for the CA(2 of 3), DE, FL, and SC trials.

Geographic representation is adequate since the test states of CA(18%), FL(23%), MD(<0.5%), NC(10%), NJ(7%), SC(<0.5%), TX(16%) and WI(1%) accounted for ca. 75% of the U.S. pepper acreage (1982 Census of Agriculture, Vol. 1, Part 51, pp. 349-350). The submitted field trial data for peppers are not adequate because no data reflecting application at 1x, according to current label directions, were provided. In addition, current product label(s) do not specify a PHI and a maximum number of applications per growing season or a maximum seasonal rate for all formulations. The available data indicate that fluoride residues of cryolite will not exceed the established tolerance of 7.0 ppm in/on peppers harvested 14 days following two foliar applications of the 96% WP at ca. 0.2x the maximum registered single application rate.



### Magnitude of the Residue in Tomatoes

A tolerance of 7.0 ppm has been established for the combined residues of the insecticidal fluorine compounds cryolite and synthetic cryolite, sodium aluminum fluoride, in/on tomatoes [40 CFR §180.145(a)].

The 96% WP and WP/D formulations are registered for multiple foliar applications to tomatoes at 14-48 lb ai/A/application as a spray or dust. The 50 and 72% D formulations are registered for multiple foliar applications to tomatoes at 13-30 lb ai/A/application. The 46 and 48% D MAI formulations are registered for similar use at 10-22 lb ai/A. Applications may be made with ground or aerial equipment. No applications may be made under drift conditions, in irrigation systems, or in combination with lime. Excess residues on edible portions are to be removed by washing, brushing, or by other effective means. A 1-day PHI exists for applications of the 48% D MAI at <15.8 lb ai/A and for the 46% D MAI at all application rates; a 5-day PHI exists for applications of the 48% D MAI at >15.8 lb ai/A. No PHI has been established for any of the other formulations. There is no established maximum seasonal rate or maximum number of applications per season for any formulation. [These use directions were obtained from the label for EPA Reg. No. 4581-116 accepted 9/14/92 and from the following product labels certified and submitted in response to the 10/6/89 DCI for Lists A and B product labels: EPA Reg. Nos. 10163-22, 10163-25, 10163-40, and 10163-41, and 10163-66. We note that these use directions are not in agreement with proposed labels submitted by Atochem and Gowan in 1990 and reviewed in the Cryolite Update dated 5/16/91.]

Atochem and Gowan (1993; MRID 42656901) submitted data from 4 tests conducted in CA(3) and FL (1) depicting fluoride residues of cryolite in/on tomatoes harvested 14 days following the last of four postemergence foliar broadcast applications of the 96% WP formulation at 15.4 lb ai/A/application (ca. 0.3x the maximum registered single application rate). Applications were made at 6- to 8-day intervals to tomato plants bearing immature and mature fruit using ground (52-74 gal/A of finished spray) and aerial (8.6-10.4 gal/A of finished spray) equipment. The results of the tomato field trials are presented in Table 3. Apparent residues in/on untreated samples were 1.69-3.60 ppm. No explanation was provided by the registrant regarding the presence of detectable residues in the control samples. However, it should be noted that fluoride is widely distributed in the earth's crust (ca. 0.03%). Samples were frozen immediately after collection and stored at ca. -20 C for up to 8 months. Samples were analyzed for fluoride residues of cryolite using Atochem Method No. BR-006-01.

Table 3. Fluoride residues of cryolite in/on tomatoes following four applications of the 96% WP formulation at ca. 0.3x the maximum registered single application rate.

Equipment	Test States	Number of Samples	Cryolite, ppm <sup>a</sup>
Aerial	CA	8	2.86-5.50
Ground	CA, FL	5	3.49-6.06
Control	CA, FL	4	2.48-3.96

<sup>a</sup> Residue values were not corrected for method recoveries and were not corrected for fluoride levels in controls.

Geographic representation is adequate since the test states of CA(81%) and FL(6%) account for 87% of the 1990 U.S. tomato acreage (Agricultural Statistics 1991, USDA). The submitted field

trial data for tomatoes are not adequate because data reflecting application at 1x, according to current label directions, were not provided. In addition, current product label(s) do not specify a PHI and a maximum number of applications per season or a maximum seasonal rate for all formulations. The available data indicate that fluoride residues of cryolite will not exceed the established tolerance of 7.0 ppm in/on tomatoes harvested 14 days following four foliar applications of the 96% WP formulation at 0.3x the maximum registered single application rate. Additional data are required.

#### EPA MEMORANDA CITED IN THIS REVIEW

CBTS No(s).        PP# 9F3739  
 Subject:        Cryolite on Potatoes. Evaluation of Petition Method Validation Results.  
 From:        F. Griffith  
 To:        D. Edwards  
 Date:        5/19/93

#### MASTER RECORD IDENTIFICATION NUMBERS

Citations for the MRID documents referred to in this review are presented below.

42630001 Pitt, J.L. (1993) Elf Atochem Method Number BR-010-0; Kryocide® Insecticide Analytical Fluoride Electrode Method for Cryolite in Tissue Samples by Microdiffusion. Laboratory Project ID Number BR-92-55. Unpublished study conducted by Elf Atochem and submitted by Elf Atochem North America, Inc. Philadelphia, PA and Gowan Company, Yuma, AZ. 17 p.

42659301 Pitt, J.L. (1993) Kryocide®: Magnitude of the Residues in Pepper. Laboratory Project ID Number BR-91-07-1. Unpublished study conducted by Elf Atochem and McKenzie Laboratories, Inc. and submitted by Elf Atochem North America, Inc. Philadelphia, PA and Gowan Company, Yuma, AZ. 540 p.

42656901 Pitt, J.L. (1993) Kryocide®: Magnitude of the Residue in Tomato. Laboratory Project ID Number BR-90-29-1. Unpublished study conducted by Elf Atochem and McKenzie Laboratories, Inc. and submitted by Elf Atochem North America, Inc. Philadelphia, PA and Gowan Company, Yuma, AZ. 215 p.

DP BARCODE: D188947

REREG CASE #

CASE: 819150  
SUBMISSION: S436616DATA PACKAGE RECORD  
BEAN SHEETDATE: 03/08/93  
Page 1 of 1

## \* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REREGISTRATION ACTION: 627 GENERIC DATA SUBMISSION  
CHEMICALS: 075101 Cryolite

100.00 %

ID#: 075101

COMPANY:

PRODUCT MANAGER: 72 LARRY SCHNAUBELT 703-308-8058 ROOM: CS1 3C3

PM TEAM REVIEWER: BRIGID LOWERY 703-308-8053 ROOM: CS1 3G6

RECEIVED DATE: 01/21/93 DUE OUT DATE: 01/21/94

## \* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 188947 EXPEDITE: N DATE SENT: 03/08/93 DATE RET.: / /

CHEMICAL: 075101 Cryolite

DP TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 03/08/94 CSF: N

LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : HED	/ /	/ /
BRAN:	/ /	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

## \* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

PLEASE REVIEW THE (2) ATTACHED STUDIES SUBMITTED TO  
SUPPORT THE REREGISTRATION OF CRYOLITE.

MRID - 42630001 - 171-4c &amp; d

MRID - 42656901 - 171-4k (TOMATOES)


*gilling Bonnie (Mark Metzger)*

## \* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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**elf atochem**

Elf Atochem North America, Inc.  
Three Parkway, Philadelphia, PA 19102  
Tel: (215) 587-7000

426569- 

**VIA CERTIFIED MAIL**

January 15, 1993

Office of Pesticide Programs  
Document Processing Desk (RS-0087)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

Re: Cryolite Case No.: 0087  
Submission of Magnitude of the Residue - Tomato 171-4 (K)  
and Revised Cryolite Tissue Method  
Kryocide® Insecticide EPA Reg. No. 4581-116  
Prokil Cryolite Insecticide, EPA Reg. No. 10163-41

Dear Ms. Lowery:

Elf Atochem North America, Inc. and Gowan Company, under Company Number 62569 submit 3 volumes plus administrative documents to satisfy data requirements of EPA for products containing cryolite.

The following study requested by EPA is submitted herein:

Kryocide® Magnitude of the Residue in Tomato 11/20/92.  
Atochem Study Number: BR-90-29

In this study applications were made by both ground and aerial equipment to field trials conducted in California and Florida. Four (4) applications of the 96% wettable powder formulation at 15.4 lbs a.i. per acre at 6-8 day intervals with a 14 day PHI. The study fulfills data required by the Registration Standard and the July 6, 1992 Cryolite Residue Chemistry Review.

Also enclosed is:

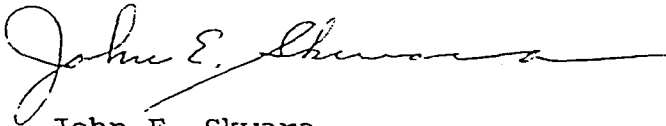
Kryocide® Insecticide Analytical Fluoride Electrode Method for cryolite in Tissue Samples by Microdiffusion. 12/15/92 Atochem Study Number BR-92-55.

Office of Pesticide Programs  
January 15, 1993  
Page 2

These are revisions to Elf Atochem Method Number BR-010-00. Recommendations made by EPA in a CBTS Memorandum dated May 19, 1992 identified as PP# 9F3739: Evaluation of the Petition Method Validation Results of the Revised Methods are incorporated into this document. The revised tissue method was required by the July 6, 1992 Cryolite Residue Chemistry Review.

Please do not hesitate to contact me for additional information or any questions you may have.

Sincerely,

A handwritten signature in cursive script, appearing to read "John E. Skwara", followed by a horizontal line.

John E. Skwara  
Registration Specialist  
Agrichemicals Division  
(215) 587-7303

Enclosures

cc: B. Codrea - Gowan Company  
R. Forrest - EPA Registration Division  
B. Lowery - EPA Special Review & Reregistration Division

File: Kryocide - Residue Chemistry EPA Corr.

office.jes

TRANSMITTAL DOCUMENT1. Name and Address of Submitter

*Atochem North America	Gowan Company
Agchem Division	1644 Engler Avenue
Three Parkway, Room 619	Yuma, AZ 85366-5569
Philadelphia, PA 19102	

\* Atochem will act as sole submitter under Company No. 62569.

2. Regulatory Action in Support of which this Package is Submitted

Submitted as Required by the Cryolite Registration Standard - EPA  
Case No. 0087 and Residue Chemistry Review of July 6, 1992.

3. Transmittal Date: January 15, 19924. List of Submitted Studies:

MRID

Vol. 1 Administrative Documents

42656901

Vol. (2)

KRYOCIDE: Magnitude of the Residue  
in Tomato. Guideline No. 171-4,  
McKenzie Laboratories, Inc.,  
Atochem Study No. 90-29, November  
20, 1992.

42630001

Vol. 3

Kryocide Insecticide - Analytical  
Fluoride Electrode Method for  
Cryolite in Tissue Samples by  
Microdiffusion. Guideline No. 171-4,  
Elf Atochem North America, Study No.  
BR-92-55, December 15, 1992.

Company Official: John E. Skwara

  
Signature

Company Name: Atochem North America - Agchem Division

Company Contact: John E. Skwara

Telephone: (215) 587-7303

DP BARCODE: D188944

REREG CASE #

CASE: 819150  
SUBMISSION: S436613DATA PACKAGE RECORD  
BEAN SHEETDATE: 03/08/93  
Page 1 of 1

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CASE TYPE: REREGISTRATION ACTION: 627 GENERIC DATA SUBMISSION  
CHEMICALS: 075101 Cryolite

100.00 %

ID#: 075101

COMPANY:

PRODUCT MANAGER: 72 LARRY SCHNAUBELT 703-308-8058 ROOM: CS1 3C3

PM TEAM REVIEWER: BRIGID LOWERY 703-308-8053 ROOM: CS1 3G6

RECEIVED DATE: 02/10/93 DUE OUT DATE: 02/10/94

## \* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 188944 EXPEDITE: N DATE SENT: 03/08/93 DATE RET.: / /

CHEMICAL: 075101 Cryolite

DP TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 03/08/94

CSF: N

LABEL: N

ASSIGNED TO	DATE	IN	DATE	OUT
DIV : HED	/	/	/	/
BRAN:	/	/	/	/
SECT:	/	/	/	/
REVR :	/	/	/	/
CONTR:	/	/	/	/

## \* \* \* DATA REVIEW INSTRUCTIONS \* \* \*


PLEASE REVIEW THE ATTACHED STUDY SUBMITTED TO  
SUPPORT THE REREGISTRATION OF CRYOLITE  
MRID - 42659301 - 171-4K (PEPPERS)

## \* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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Elf Atochem North America, Inc.  
Three Parkway, Philadelphia, PA 19102  
Tel: (215) 587-7000

426593- 

**VIA CERTIFIED MAIL**

February 3, 1993

Office of Pesticide Programs  
Document Processing Desk (RS-0087)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

**Re: Cryolite Case No.: 0087**  
**Submission of Magnitude of the Residue - Pepper 171-4 (K)**  
**Kryocide® Insecticide EPA Reg. No. 4581-116**  
**Prokil Cryolite Insecticide, EPA Reg. No. 10163-41**

Dear Ms. Lowery:

Elf Atochem North America, Inc. and Gowan Company, under Company Number 62569 submit 3 volumes plus administrative documents to satisfy data requirements of EPA for products containing cryolite.

The following study requested by EPA is submitted herein:

Kryocide®: Magnitude of the Residue in Pepper Dated:  
January 11, 1993  
Atochem Study Number: BR-91-07

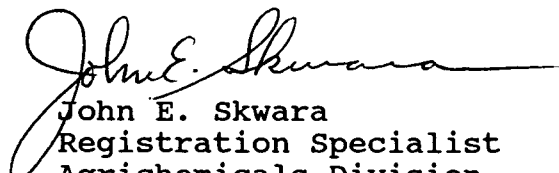
In this study applications were made by both ground and aerial equipment to field trials conducted in California, Delaware, Florida, North Carolina, New Jersey, South Carolina, Texas and Wisconsin. Two (2) applications of the 96% wettable powder formulation at 11.5 lbs a.i. per acre at 7-9 day intervals with a 14 day PHI were made. The study fulfills data required by the Registration Standard and the July 6, 1992 Cryolite Residue Chemistry Review.



Office of Pesticide Programs  
February 3, 1993  
Page 2

Please do not hesitate to contact me for additional information  
or any questions you may have.

Sincerely,

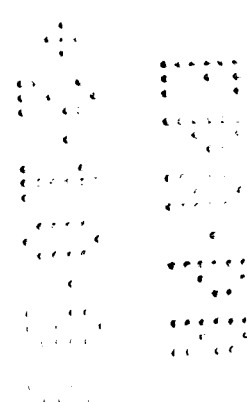
  
John E. Skwara  
Registration Specialist  
Agriculture Division  
(215) 587-7303

Enclosures

cc: B. Codrea - Gowan Company  
R. Forrest - EPA Registration Division  
B. Lowery - EPA Special Review & Reregistration Division

File: Kryocide - Residue Chemistry EPA Corr.

office.jes



**TRANSMITTAL DOCUMENT****1. Name and Address of Submitter**

\*Atochem North America      Gowan Company  
Agchem Division      1644 Engler Avenue  
Three Parkway, Room 619      Yuma, AZ 85366-5569  
Philadelphia, PA 19102

\* Atochem will act as sole submitter under Company No. 62569.

**2. Regulatory Action in Support of which this Package is Submitted**

Required by Cryolite Registration Standard - EPA Case No. 0087 and  
Residue Chemistry Review of July 6, 1992.

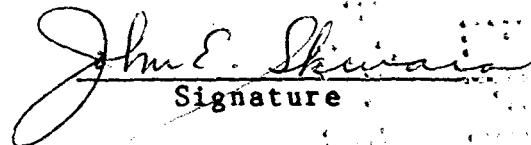
**3. Transmittal Date: February 3, 1993****4. List of Submitted Studies:****MRID**

Vol. 1      Administrative Documents

42659301

Vol. 2      KRYOCIDE: Magnitude of the Residue in  
Pepper. Guideline No. 171-4, McKenzie  
Laboratories, Inc., Project Sponsors:  
Elf Atochem North America, Inc. and  
Gowan Company, Elf Atochem Study No.  
BR-91-07, January 11, 1993.

Company Official: John E. Skwara

  
Signature

Company Name: Atochem North America - Agchem Division

Company Contact: John E. Skwara

Telephone: (215) 587-7303



13544

# R165246

**Chemical Name:** Cryolite

**PC Code:** 075101

**HED File Code:** 61300 SRRD FRN

**Memo Date:** 3/23/1994

**File ID:** DPD188947

**Accession #:** 000-00-8014

**HED Records Reference Center**  
**3/18/2009**